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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,573	06/05/2006	Naoto Nemoto	2144.0330000/RWE/RAS	3545

26111 7590 01/07/2009  
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.  
1100 NEW YORK AVENUE, N.W.  
WASHINGTON, DC 20005

EXAMINER
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LEE, JAE W

ART UNIT	PAPER NUMBER
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1656

MAIL DATE	DELIVERY MODE
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01/07/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/566,573	<b>Applicant(s)</b> NEMOTO ET AL.	
	<b>Examiner</b> JAE W. LEE	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Application status***

Claims 1-23 are pending in the instant application.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-21, drawn to a method of screening for useful proteins by synthesizing a protein comprising a disulfide bond via the introduction of cysteine residues into the amino acid sequence of the protein, and analyzing the function of the protein, wherein the method comprises the steps of: (a) preparing one or more mRNAs encoding a protein/proteins that comprise at least two cysteine residues, and linking each of the prepared mRNAs with puromycin or a puromycin-like compound to obtain mRNA-puromycin conjugate(s); (b) contacting a translation system with the mRNA-puromycin conjugate(s) obtained in step (a) to synthesize the protein/proteins, and preparing mRNA-puromycin- protein conjugate(s); and (c) contacting one or more target substances with the mRNA-puromycin-protein conjugate(s) prepared in step (b), and determining whether the target substances interact with any one of the proteins within the mRNA-puromycin-protein conjugate(s).

Group II, claim(s) 22, drawn to a synthetic protein-puromycin conjugate obtainable by the method of claim 1 or 3, which has 8 to 500 amino acid residues, comprises 2 to 10 cysteine residues for forming disulfide bonds, and has an association constant to the target substance that changes due to oxidation and reduction.

Group III, claim(s) 23, drawn to a synthetic protein, which is not a protein-puromycin conjugate, which has 8 to 500 amino acid residues, comprises 2 to 10 cysteine residues for forming disulfide bonds, and has an association constant to the target substance that

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changes due to oxidation and reduction.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Tabuchi et al. (FEBS Letters, 508 (2001), 309-312, see IDS) teach a method comprising steps: (a) preparing a mRNAs encoding His- or Flag-tagged GFP that comprising at least two cysteine residues, and linking each of the prepared mRNAs with puromycin to obtain mRNA-puromycin conjugates (see Figures 1 and 2 and related sections under Materials and Methods); (b) contacting a translation system, i.e., in vitro translation system (see section 2.3 under Materials and Methods) with the mRNA-puromycin conjugates obtained in step (a) to synthesize the His- or Flag-tagged GFP, and preparing mRNA-puromycin-protein conjugates; and (c) contacting target substances, i.e., fluorescein-dC-puromycin, Ni-NTA or anti-Flag M2 antibody, with the mRNA-puromycin-protein conjugates prepared in step (b), and determining whether the target substances interact with said protein conjugates, which anticipates the limitation of claim 1, in the recitation of "A method of screening for useful proteins by synthesizing a protein comprising a disulfide bond via the introduction of cysteine residues into the

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amino acid sequence of the protein, and analyzing the function of the protein, wherein the method comprises the steps of: (a) preparing one or more mRNAs encoding a protein/proteins that comprise at least two cysteine residues, and linking each of the prepared mRNAs with puromycin or a puromycin-like compound to obtain mRNA-puromycin conjugate(s); (b) contacting a translation system with the mRNA-puromycin conjugate(s) obtained in step (a) to synthesize the protein/proteins, and preparing mRNA-puromycin- protein conjugate(s); and (c) contacting one or more target substances with the mRNA-puromycin-protein conjugate(s) prepared in step (b), and determining whether the target substances interact with any one of the proteins within the mRNA-puromycin-protein conjugate(s),” and thus, the shared technical feature of the groups is not a “special technical feature”, unity of invention between the groups does not exist. It is also noted that there is no “special technical feature” shared by Groups II and III because the synthetic protein of Group III does not have to be a puromycin-conjugate, and as such, it can be completely unrelated structurally and functionally to the synthetic protein of Group II.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/JAE W LEE/

Examiner, Art Unit 1656

/Rebecca E. Prouty/

Primary Examiner,

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